TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-19-0148, P-19-0149, P-19-0150, and P-19-0151

Number: P-19-0148, P-19-0149, P-19-0150, and P-19-0151
TSCA Section 5(a)(3) Determination: The chemical substances are not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:

Generic (P-19-0148): Iron, complexes with ethylenediamine-4-hydroxycarbomonocycle hetero-acid-2-oxoacetic acid reaction products, potassium salts

Generic (P-19-0149): Iron, complexes with ethylenediamine-4-hydroxycarbomonocycle hetero-acid potassium salt (1:1)-potassium 2-oxoacetate (1:1) reaction products, potassium salts

Generic (P-19-0150): Iron, complexes with ethylenediamine-4-hydroxycarbomonocycle hetero-acid-2-oxoacetic acid reaction products, sodium salts

Generic (P-19-0151): Iron, complexes with ethylenediamine-4-hydroxycarbomonocycle hetero-acid sodium salt (1:1)-sodium 2-oxoacetate (1:1) reaction products, sodium salts

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Import for use as fertilizer ingredients, consistent with manufacturing, processing, use, distribution, and disposal information described in the PMNs.
Known conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are known conditions of use and found none.
Reasonably foreseen conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are reasonably foreseen conditions of use and found none.

Summary: The chemical substances are not likely to present an unreasonable risk of injury to

[1] Under TSCA § 3(4), the term "conditions of use" means "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." In general, EPA considers the intended conditions of use of a new chemical substance to be those identified in the section 5(a) notification. Known conditions of use include activities within the United States that result from manufacture that is exempt from PMN submission requirements. Reasonably foreseen conditions of use are future circumstances, distinct from known or intended conditions of use, under which the Administrator expects the chemical substance to be manufactured, processed, distributed, used, or disposed of. The identification of "reasonably foreseen" conditions of use will necessarily be a case-by-case determination and will be highly fact-specific. Reasonably foreseen conditions of use will not be based on hypotheticals or conjecture. EPA's identification of conditions of use includes the expectation of compliance with federal and state laws, such as worker protection standards or disposal restrictions, unless case-specific facts indicate otherwise. Accordingly, EPA will apply its professional judgment, experience, and discretion when considering such factors as evidence of current use of the new chemical substance outside the United States, evidence that the PMN substance is sufficiently likely to be used for the same purposes as existing chemical substances that are structurally analogous to the new chemical substance, and conditions of use identified in an initial PMN submission that the submitter omits in a revised PMN. The sources EPA uses to identify reasonably foreseen conditions of use include searches of internal confidential EPA PMN databases (containing use information on analogue chemicals), other U.S. government public sources, the National Library of Medicine's Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REACH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.

health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, based on the risk assessment presented below.

Although EPA estimated that the new chemical substances could be very persistent, the substances have low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms.

Based on test data on analogous chemical substances, EPA estimates that the chemical substances have moderate environmental hazard and potential for the following human health hazards: systemic effects and developmental effects. EPA concludes that the new chemical substances are not likely to present an unreasonable risk under the conditions of use.

Fate: Environmental fate is the determination of which environmental compartment(s) a chemical moves to, the expected residence time in the environmental compartment(s) and removal and degradation processes. Environmental fate is an important factor in determining exposure and thus in determining whether a chemical may present an unreasonable risk. EPA estimated physical/chemical and fate properties of the new chemical substances' anions using data for analogue(s) (soluble compounds with high molecular volume) and of the cations using data available for analogue(s) (metals) and data available for the cations. In wastewater treatment, the anions are expected to be removed with an efficiency of 0% to 90% due to possible biodegradation and the cations are expected to be removed with an efficiency of 80% due to sorption. Removal of the anions by biodegradation is unknown, destruction (mineralization) of the anions by biodegradation is partial, and removal of the cations by biodegradation is negligible. Sorption of the anions to sludge, soil, and sediment is expected to be low and sorption of the cations to sludge is strong. Migration of the anions to groundwater is expected to be rapid due to low sorption to soil and sediment. Due to low estimated vapor pressure and Henry's law constant, the new chemical substances are expected to undergo negligible volatilization to air. Overall, these estimates indicate that the anions have low potential to volatilize to air and have high potential to migrate to groundwater; and that the cations have low potential to volatilize to air.

Persistence[2]: Persistence is relevant to whether a new chemical substance is likely to present an unreasonable risk because chemicals that are not degraded in the environment at rates that prevent substantial buildup in the environment, and thus increase potential for exposure, may present a risk if the substance presents a hazard to human health or the environment. EPA estimated degradation half-lives of the new chemical substances' anions using data for analogue(s) and of the cations using data available for analogue(s) (metals). EPA estimated that the anions' aerobic biodegradation half-lives are 2 to 6 months and anaerobic biodegradation half-lives are > 6 months; and that the cations' aerobic and anaerobic biodegradation half-lives are > 6 months. These estimates indicate that the new chemical substances may be very

[2] Persistence: A chemical substance is considered to have limited persistence if it has a half-life in water, soil or sediment of less than 2 months or there are equivalent or analogous data. A chemical substance is considered to be persistent if it has a half-life in water, soil or sediments of greater than 2 months but less than or equal to 6 months or if there are equivalent or analogous data. A chemical substance is considered to be very persistent if it has a half-life in water, soil or sediments of greater than 6 months or there are equivalent or analogous data. (64 FR 60194; November 4, 1999)

persistent in anaerobic environments (e.g., sediment), that the anions may be persistent in aerobic environments (e.g., surface water), and that the cations may be very persistent in aerobic environments (e.g., surface water).

Bioaccumulation[3]: Bioaccumulation is relevant to whether a new chemical substance is likely to present an unreasonable risk because substances that bioaccumulate in aquatic and/or terrestrial species pose the potential for elevated exposures to humans and other organisms via food chains. EPA estimated the potential for the new chemical substances' anions to bioaccumulate using data for analogue(s) (soluble compounds with high molecular volume) and of the cations to bioaccumulate using data available for analogue(s) (metals). EPA estimated that the anions have low bioaccumulation potential based on high water solubility, which increases elimination, and the cations have low bioaccumulation potential based on bioconcentration or bioaccumulation data reported for metals. Although EPA estimated that the new chemical substancescould be very persistent, the substances have low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms.

Human Health Hazard[4]: Human health hazard is relevant to whether a new chemical substance is likely to present an unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated the human health hazard of these chemical substances based on their estimated physical/chemical properties, and by comparing them to structurally analogous chemical substances for which there is information on human health hazard. Absorption is expected to be nil through the skin for the neat materials and poor when in solution, poor through the GI tract, and good through the lungs based on physical/chemical properties. For the new

[3] Bioaccumulation: A chemical substance is considered to have a low potential for bioaccumulation if there are bioconcentration factors (BCF) or bioaccumulation factors (BAF) of less than 1,000 or there are equivalent or analogous data. A chemical substance is considered to be bioaccumulative if there are BCFs or BAFs of 1,000 or greater and less than or equal to 5,000 or there are equivalent or analogous data. A chemical substance is considered to be very bioaccumulative if there are BCFs or BAFs of 5,000 or greater or there are equivalent or analogous data. (64 FR 60194; November 4 1999)

[4] A chemical substance is considered to have low human health hazard if effects are observed in animal studies with a No Observed Adverse Effect Level (NOAEL) equal to or greater than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have moderate human health hazard if effects are observed in animal studies with a NOAEL less than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have high human health hazard if there is evidence of adverse effects in humans or conclusive evidence of severe effects in animal studies with a NOAEL of less than or equal to 10 mg/kg/day or if there are equivalent data on analogous chemical substances. EPA may also use Benchmark Dose Levels (BMDL) derived from benchmark dose (BMD) modeling as points of departure for toxic effects. See https://www.epa.gov/bmds/what-benchmark-dose-software-bmds. Using this approach, a BMDL is associated with a benchmark response, for example a 5 or 10 % incidence of effect. The aforementioned characterizations of hazard (low, medium, high) would also apply to BMDLs. In the absence of animal data on a chemical or analogous chemical substance, EPA may use other data or information such as from in vitro assays, chemical categories (e.g., Organization for Economic Co-operation and Development, 2014 Guidance on Grouping of Chemicals, Second Edition. ENV/JM/MONO(2014)4. Series on Testing & Assessment No. 194. Environment Directorate, Organization for Economic Co-operation and Development, Paris, France. (http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en)), structure-activity relationships, and/or structural alerts to support characterizing human health hazards.

chemical substances, EPA identified systemic and developmental effects as hazards. EPA identified a NOAEL of 20 mg/kg/day based on systemic effects, which is protective for all health effects identified, and was used to derive exposure route- and population-specific points of departure.

Environmental Hazard[5]: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard of these new chemical substances using hazard data on an analogous chemical. These substances fall within the TSCA New Chemicals Category of Polyanionic Polymers (and Monomers). Acute toxicity values estimated for fish, aquatic invertebrates, and algae are > 93.1 mg/L, > 98.3 mg/L, and 32.22 mg/L, respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are > 9.3 mg/L (analogue with ACR of 10), > 9.8 mg/L (analogue with ACR of 10), and 10 mg/L, respectively. These toxicity values indicate that the new chemical substances are expected to have moderate environmental hazard. Application of assessment factors of 4 and 10 to acute and chronic toxicity values, respectively, results in acute and chronic concentrations of concern of 8.055 mg/L (8,055 ppb) and 1 mg/L (1,000 ppb), respectively.

Exposure: The exposure to a new chemical substance is potentially relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance.

EPA estimates occupational exposure and environmental release of the new chemical substance under the intended conditions of use described in the PMN using ChemSTEER (Chemical Screening Tool for Exposures and Environmental Releases; https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases). EPA uses EFAST (the Exposure and Fate Assessment Screening Tool; https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014) to estimate general population, consumer, and environmental exposures.

EPA considers workers to be a potentially exposed or susceptible subpopulation (PESS) on the basis of greater exposure potential compared to the general population. EPA also considers PESS in conducting general population drinking water exposures by evaluating risks associated with water intake rates for multiple age groups, ranging from infants to adults. EPA considers

[5] A chemical substance is considered to have low ecotoxicity hazard if the Fish, Daphnid and Algae LC50 values are greater than 100 mg/L, or if the Fish and Daphnid chronic values (ChVs) are greater than 10.0 mg/L, or there are not effects at saturation (occurs when water solubility of a chemical substance is lower than an effect concentration), or the log Kow value exceeds QSAR cut-offs. A chemical substance is considered to have moderate ecotoxicity hazard if the lowest of the Fish, Daphnid or Algae LC50s is greater than 1 mg/L and less than 100 mg/L, or where the Fish or Daphnid ChVs are greater than 0.1 mg/L and less than 10.0 mg/L. A chemical substance is considered to have high ecotoxicity hazard, or if either the Fish, Daphnid or Algae LC50s are less than 1 mg/L, or any Fish or Daphnid ChVs is less than 0.1 mg/L (Sustainable Futures https://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-manual).

consumers of specific products to be a potentially exposed or susceptible subpopulation on the basis of greater exposure potential compared to the general population who do not use specific products.

For these new chemical assessments, EPA assessed worker exposure via inhalation and dermal contact. Releases to water, air, and landfill were estimated. Exposure to the general population was assessed via drinking water, landfill leachate and fugitive air releases. Exposure to consumers was assessed via inhalation and dermal exposure.

Risk Characterization: EPA applies a margin of exposure approach to calculate potential human health risks of new chemicals. A benchmark (acceptable) margin of exposure is derived by applying uncertainty factors for the following types of extrapolations: intra-species extrapolation (UF_H = 10 to account for variation in sensitivity among the human population), inter-species extrapolation (UF_A = 10 to account for extrapolating from experimental animals to humans) and LOAEL-to-NOAEL extrapolation (UF_L = 10 to account for using a LOAEL when a NOAEL is not available). Hence, in the New Chemicals Program, a benchmark MOE is typically 100 and 1,000 when NOAELs and LOAELs, respectively, are used to identify hazard. When allometric scaling or pharmacokinetic modeling is used to derive an effect level, the UF_H may be reduced to 3, for a benchmark MOE of 30. The benchmark MOE is used to compare to the MOE calculated by comparing the toxicity NOAEL or LOAEL to the estimated exposure concentrations. When the calculated MOE is equal to or exceeds the benchmark MOE, the new chemical substance is not likely to present an unreasonable risk. EPA assesses risks to workers considering engineering controls described in the PMN but in the absence of personal protective equipment (PPE) such as gloves and respirators. If risks are preliminarily identified, EPA then considers whether the risks would be mitigated by the use of PPE (e.g., impervious gloves, respirator).

Risks to human health for the new chemical substances were evaluated using the route-specific effect levels (i.e., NOAEL). No acute hazards were identified for the new chemical substances; therefore, risks were not evaluated for workers via dermal and inhalation exposures, which are expected to occur [claimed CBI]. Risks were not evaluated for workers for systemic effects via dermal and inhalation exposure since subchronic exposures are not expected.

Risks were not identified for the general population for systemic effects via drinking water exposure based on quantitative hazard data for an analogue (MOE_{adult}=2,198, MOE_{infant}=523, $MOE_{landfill}$=42,900; Benchmark MOE=100). No acute hazards were identified for the new chemical substances; therefore, risks were not evaluated for the general population via fugitive inhalation exposures which are expected to occur [claimed CBI]. Risks were not evaluated for the general population for systemic effects via fugitive inhalation exposure since subchronic exposures are not expected.

Risks were not identified for consumers for systemic effects via dermal or inhalation exposure based on quantitative hazard data for an analogue (MOE_{dermal}=6,200, $MOE_{inhalation}$=100,000; Benchmark MOE=100).

Environmental Risk: Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Risks from acute exposure to the environment were not identified due to releases to water (surface water

concentration [SWC]: 804 ppb) that did not exceed the acute COC (8,055 ppb). Risks from chronic exposure to the environment were not identified due to the lack chronic releases to water for the new chemical substance.

Because worker exposures can be controlled by PPE and no unreasonable risks to the general population, consumers, or the environment were identified, EPA has determined that the new chemical substances are not likely to present unreasonable risk to human health or the environment under the conditions of use.

12/16/2019
Date:

/s/
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